U.S. Patent Law Update
On Sale Bar (2019)

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Pre-AIA 35 U.S.C. 102(b)

- A person shall be entitled to a patent unless —
- (b) the invention was…in public use or **on sale** in this country, more than one year prior to the date of the application for patent in the United States

- It was well established that the offer to sell or sale did not have to be made public for the on sale bar to apply

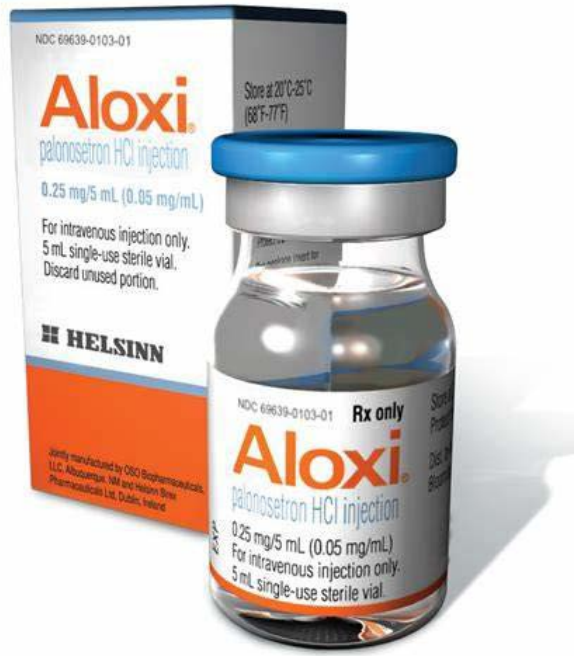
AIA 35 U.S.C. 102

- A person shall be entitled to a patent unless –
- the claimed invention was . . . in public use, **on sale**, or **otherwise available to the public** before the effective filing date of the claimed invention
- The 1-year grace period still applies under AIA

- **Issue:**
- Does the catchall phrase of "otherwise available to the public" alter the meaning of "on sale"?

Helsinn Healthcare S.A. v. Teva Pharmaceuticals, USA, Inc. (2019)

- Helsinn Healtchare S. A., a Swiss pharmaceutical company developed Aloxi (palonosetron), a drug that treats chemotherapy-induced nausea.
- Helsinn entered into **confidential** license, supply, and purchase agreements for Aloxi (0.25 mg dose) with MGI Pharma, Inc. of Minnesota
- Helsinn and MGI announced the agreements in a joint press release, and Helsinn reported the agreements in its SEC filings. However, **neither the press release nor the SEC filings disclosed the details of the invention**.
- Nearly two years after the agreements, Helsinn sought patent protection for Aloxi in the United States.
- Teva sought to market a generic of Aloxi and Helsinn filed an infringement suit.
- Teva asserted invalidity of the patent due to the on sale bar.



Path to Supreme Court

DISTRICT COURT

CAFC (COURT OF APPEALS FOR THE FEDERAL CIRCUIT)

SUPREME COURT

District Court

- The District Court concluded that, under the AIA, an invention is not “on sale” unless the sale or offer in question made the claimed invention available to the public.
- Because the companies’ public disclosure of the agreements between Helsinn and MGI did not disclose the 0.25 mg dose, the claimed invention was not “on sale.”

Court of Appeals for the Federal Circuit (CAFC)

- The Federal Circuit reversed and held that the patent was invalid due to the on sale bar.
- The Federal Circuit relied on the fact that the **existence of the sales contracts was publicly known**, even if the details of the invention (e.g. 0.25 mg dose) was kept confidential.

Supreme Court

- The Supreme Court affirmed the Federal Circuit's decision, but based **its decision on the mere offer of the sale**; **it was irrelevant whether the sale itself was publicized.**

- **Result**: Helsinn's patent is invalid and Teva is free to market the generic version of Aloxi.

Supreme Court's Rationale

- In 1998, the Supreme Court already decided the meaning of "on sale." (*Pfaff*)
- 1. The product must be the subject of a commercial offer for sale; and
- 2. The invention must be ready for patenting (can be satisfied by two ways)
  - reduction to practice
  - drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention

Supreme Court's Rationale

- The addition of "or otherwise available to the public" is simply not enough of a change for us to conclude that Congress intended to alter the meaning of the reenacted term "on sale."

Takeaways

- An **offer** for sale, whether or not the public has access to this information, can be enough to invoke the on sale bar under 35 U.S.C. 102
- Inventors should ideally file at the time an invention is first commercialized or at least within one year of commercialization
- Remember the Public Use Bar!
- Provisional
- The most risk-averse strategy is to file a patent application before making any disclosures to third parties, especially when the disclosure is for the purpose of commercial gain

Any Questions?

THANK YOU!

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